

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and these remarks.

I. Status of the Claims

Claims 2-12 and 25-29 were cancelled previously. Claim 1 has been amended for greater clarity. Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry of this response, claims 1 and 13-24 will be pending.

II. Rejection of Claims under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1 and 13-24 for alleged lack of enablement. Applicants respectfully traverse the rejection.

The Examiner is heard to argue that the claimed method requires the first reaction to be complete but that “it cannot be conclusively determined from the disclosure that the first reaction step is run to completion” (action at page 5, lines 1 and 2). Yet, the specification describes both the preferred temperature range for carrying out the first reaction (about 30°C to 40°C, and preferably 37°C) and the required reaction time (from about 2 minutes to 10 minutes). *See* page 13, third full paragraph. Contrary to the Examiner’s contention, therefore, one skilled in the art could readily determine, in view of Applicants’ teachings, the conditions to complete the first reaction.

Furthermore, the specification discloses that the readings of absorbance at certain wavelengths are compared to the standard curve or calibration curve obtained from a sample of known concentration to measure the cholesterol level. *See* page 20, lines 12-14. It is well within the reach of one skilled in the art -- indeed, it is a common practice -- to pre-establish a calibration curve to determine the concentration of a sample based on the absorbance readings. Accordingly, there is no reasonable basis to question whether the specification satisfies the

“enablement” requirement by allowing one skilled in the art to carry out the claimed methodology with only routine experimentation.

The Examiner further challenges the enabling quality of the specification by alleging the non-existence of surfactants having the specificity suitable for achieving the desired results of the invention. *See* Office Action, page 6, first paragraph. In particular, the Examiner asserts that (i) “the surfactants of both the first and second reagents can both be capable of acting non-selectively on all lipoproteins” and (ii) “both surfactants even in the preferred embodiments have HLB values that at least are capable of overlapping at the HLB value of 13” (*id.* at page 5, last four lines, and at page 6, lines 1-3). These assertions appear to stem from a misunderstanding of the claimed invention, however, and do not warrant the rejection in question.

First, the application describes that “a preferable example of a surfactant acting on lipoproteins other than LDL...is used in the first step...” (page 12, lines 7-14) and that the surfactant used in the second step is “a surfactant acting on at least LDL” (page 13, lines 24-25). As such, the surfactants have different specificities.

Second, the application teaches that the HLB value of the surfactant used in the first reaction is “13 or more and 15 or less” (page 12, line 9), which can be represented as “ $13 \leq \text{HLB} \leq 15$.” The HLB value of the surfactant for the second reaction is “11 or more and less than 13” (page 15, lines 7-8), which translates into “ $11 \leq \text{HLB} < 13$.” Consequently, the HLB values of the surfactants do not overlap at value 13, contrary to the Examiner contention.

In view of the foregoing, Applicants respectfully request withdrawal of the lack-of-enablement rejection.

III. Rejection of Claims under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 1 and 13-24 for alleged indefiniteness. Particularly, the Examiner alleges that the term “acts” is undefined in the specification.

Applicants respectfully direct the Examiner's attention to the specification at page 10, lines 17-19. There Applicants explicitly teach that "[s]urfactant acting on" refers to decomposition of lipoproteins and liberation of cholesterol from the lipoproteins."

Accordingly, withdrawal of the rejection is appropriate.

IV. Rejection of Claims under 35 U.S.C. §102(e)

The Examiner rejected claims 1, 13-15 and 20-22 for alleged anticipation by U.S. published application No. 2004/0126830 by Shull et al. ("Shull"). Applicants respectfully traverse the rejection.

Shull describes a test strip comprising at least two stacks or panels, which measure the total cholesterol and non-LDL cholesterol, respectively. Use of Shull's strip does not entail contacting a sample with a first reagent and a second reagent sequentially. Rather, the blood sample is in contact with both stacks simultaneously. See Examples 4 and 5 and Figures 5 and 10 of Schull.

In contrast, the claimed method requires that the first reaction is carried out before the second reaction. Since Shull thus does not teach each recited aspect of the claimed invention, the reference cannot reasonably be said to anticipate that invention.

V. Rejection of Claims under 35 U.S.C. §103(a)

Claims 1, 13-16 and 19-22 stand rejected over Shull in view of U.S. Patent No. 6,194,164 to Matsui et al. ("Matsui"). Claims 1, 13-15, 17, 18 and 20-22 also are rejected over Shull in view of U.S. Patent No. 6,794,157 to Sugiuchi ("Sugiuchi"). Finally, claims 1, 13-15 and 20-24 are rejected over Shull in view of U.S. published application No. 2003/0129681 by Kishi et al. ("Kishi"). According to the Examiner, each secondary reference discloses (i) a *Pseudomonas*-evolved cholesterol esterase, (ii) the first reagent comprising a surfactant specific for lipoproteins

other than LDL, and (iii) the first reaction carried out in the presence of lipoprotein lipase, respectively.

Even taken at face value, however, this characterization of the secondary references leaves unaddressed the above-discussed deficiency of the primary reference, namely, the failure of Shull to disclose or suggest a sequential relationship between the first reaction and the second reaction, as presently recited. Thus, the cited combination does not substantiate a *prima facie* case under Section 103, which underscores the need for a withdrawal of this rejection.

CONCLUSION

Applicants submit that the present application is in condition for allowance, and they request an early indication to this effect. Examiner Martin is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, Applicants hereby petition for such extension under 37 CFR §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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